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10/527,710	04/22/2005	Takeshi Ito	KUZ-0022	5270

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EXAMINER	
ELLIS, SUEZU Y	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,710	ITO ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

Claim Objections

Claims 8 and 9 are objected to because of the following informalities:

Claim 1 recites "**consisting essentially of**", however claim 8 recites "**further comprising** a percutaneous absorption enhancer". Claim 8 is objected to as being improper since it switches from close-ended language to open-ended language.

Claim 9 is objected to as being improper due to its dependency.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide a clear indication of what the basic and novel characteristics are, therefore the term "consisting essentially of" will be treated as being equivalent to "comprising". It appears that applicant may be attempting to eliminate the

fentanyl salt. What compound “consists essentially of” fentanyl but does not include the salt? If the compound is limited to fentanyl, then the transitional phrase should be "consisting of." For further explanation, see MPEP 2111.03 discussing the treatment of transitional phrases especially during claim amendment.

Claims not specifically addressed are considered as failing to comply with the written description due to their dependency.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, claim language recites “consisting essentially of”. It is unclear what the basic and novel characteristics are. Please clarify. For this reason, claim language will be treated as being equivalent to "comprising". See MPEP 2111.03.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (US 6,139,866) in view of Tsuruda et al. (CA 2 424 579).

With respect to claims 1 and 2, Chono et al. discloses an adhesive patch for maintaining a long-term drug efficacy comprising a backing layer and a pressure-sensitive adhesive layer formed on one side thereof (col. 5, lines 39-43), wherein the pressure-sensitive adhesive layer consists essentially of a pressure-sensitive adhesive base (col. 5, lines 19-22) and a tackifier resin (col. 3, lines 44-54). Chono et al. discloses in Example 6, fentanyl as an active ingredient in the concentration of 5% by weight (in the range of 1-6% by weight), and the pressure-sensitive adhesive base comprising polyisobutylene and a styrene/isoprene/styrene block copolymer. While Example 6 fails to illustrate the weight ratio of polyisobutylene and styrene/isoprene/styrene being in the ratio between 2:3 and 3:2, Chono et al. discloses the weight ratio of polyisobutylene to styrene/isoprene/styrene is in the range of 1:1 and 1:4 (col. 3, lines 9-10), the claimed weight ratio can be attained. However, Chono et al. also fails to expressly disclose the proportion of the polyisobutylene in the adhesive base being between 8 and 15% by weight. Tsuruda et al. discloses an adhesive patch having combination of styrene/isoprene/styrene block copolymer and polyisobutylene (pg. 23, lines 20-24). Tsuruda et al. discloses the total amount of polyisobutylene be in the range of 1-20% by weight (pg. 21, lines 9-13) and the amount of styrene/isoprene/styrene block copolymer being in the range of 15-30% by weight (pg. 20, lines 16-21), thus demonstrating the proportion of the polyisobutylene being 8-15%

by weight and a ratio of the concentration of the polyisobutylene to that of the styrene/isoprene/styrene block copolymer being in the range from 2:3 to 3:2 are attainable. It would have been an obvious design choice to one of ordinary skill in the art to modify the amount of the polymers, as desired, in order to adjust the adhesive strength and adhesion properties, as taught by Tsuruda et al. (pg. 23, line 10 - pg. 24, line 20). Further, it has been held that where the general conditions of a claim are discloses in the prior art, discover the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 3, the modified Chono et al. fails to expressly disclose the polyisobutylene consisting of a high molecular weight polyisobutylene and a low molecular weight polyisobutylene. Tsuruda et al. discloses an adhesive patch having a styrene/isoprene/styrene block copolymer and a combination of polyisobutylenes having high and low molecular weights, wherein the low molecular weight polyisobutylene is Vistanex LM-MH and the high molecular weight polyisobutylene is Vistanex MML-100 (pg. 21, lines 9-24; pg. 22, lines 10-12). It would have been obvious to one of ordinary skill in the art to utilize a combination of polyisobutylenes having high and low molecular weights in order to achieve the predictable result of improving the adhesive strength, adhesion to the skin for a long time, pain at the time of peeling, skin eruptions etc. (pg. 22, lines 19-24).

With respect to claim 7, while Example 6 fails to illustrate the tackifier resin being in the range of 40-50% by weight, Chono et al. does disclose the tackifier resin being in the range from 5-50% by weight (col. 3, lines 56-60) and Example 7 demonstrates an

adhesive patch of a similar composition having a tackifier resin at 42% by weight. It would have been obvious to one of ordinary skill in the art to modify the range of the tackifier resin, as desired, in order to regulate the viscosity and adhesive strength of the adhesive base, as taught by Tsuruda et al. (pg. 25, lines 9-25). Further, it has been held that where the general conditions of a claim are discloses in the prior art, discover the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 8 and 9, the modified Chono et al. discloses the inclusion of a percutaneous absorption enhancer in the pressure-sensitive adhesive layer, wherein the percutaneous absorption enhancer is one or more selected from a group consisting of isopropyl myristate and oleyl alcohol (col. 4, lines 6-8, 22-23).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Urquhart et al. (US 4,031,894).

With respect to claim 4, the modified Chono et al. addresses all the limitations of claims 1 and 3, however fails to expressly disclose the average molecular weight of the high molecular weight polyisobutylene being in the range of 900,000-2,500,000. Nevertheless, it is well known in the art that Vistanex MML-100 has an average molecular weight about 1,200,000, as evidenced by Urquhart et al. (col. 6, lines 10-12), thus is in the range of 900,000-2,500,000.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Scholz et al. (US 5,750,136).

With respect to claim 5, the modified Chono et al. addresses all the limitations of claims 1 and 3, however fails to expressly disclose the average molecular weight of the low molecular weight polyisobutylene being in the range of 30,000 – 65,000. Nevertheless, it is well known in the art that Vistanex LMMH has an average molecular weight about 53,000, as evidenced by Scholz et al. (col. 6, lines 21-23), thus is in the range of 30,000 – 65,000.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Higo et al. (US 5,866,157)

With respect to claim 6, while Example 6 fails to illustrate the tackifier resin being an alicyclic saturated hydrocarbon resin, the modified Chono et al. does discloses the tackifier can be Arcon P-100 (col. 3, lines 51-53). It is well known in the art that Arcon P-100 is an alicyclic saturated hydrocarbon resin, as evidenced by Higo et al. (Example 2).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Zaffaroni (US 3,598,122) and further in view of Kochinke (US 5,350,581).

With respect to claim 10, the modified Chono et al. addresses all the limitations of claim 1, however fails to expressly disclose the adhesive patch having an area of 10-

75 cm^2 at the time of application. Zaffaroni discloses utilizing a transdermal bandage having a surface area of 0.5 to 400 cm^2, where the size is dependent on the activity of the drug and the rate of its absorption through the skin (col. 6, lines 25-29). It would have been an obvious design choice to one of ordinary skill in the art to modify the surface area of the adhesive patch in order to ensure that the amount of drug entering the system appropriate for the treatment was safe and efficacious, as taught by Kochinke (US 5,350,581) (col. 1, lines 17-20).

Response to Arguments

Applicant's arguments filed March 11, 2008 have been fully considered but they are not persuasive.

Examiner notes the specification does not appear to clearly indicate what the basic and novel characteristics actually are, therefore the term "consisting essentially of" is treated as being equivalent to comprising. (See MPEP 2111.03) Therefore, the examiner's previous rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615